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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,766	08/28/2001	Harry S. Nick	UFJ-002US	2342

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

AKHAVAN, RAMIN

ART UNIT	PAPER NUMBER
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1636

124

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,766

Applicant(s)

NICK ET AL.

Examiner

Ramin (Ray) Akhavan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 3,13 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,14,16,17 and 19-30 is/are rejected.
- 7) ☒ Claim(s) 5-12 and 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/28/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

1. Applicant's election without traverse of Group II in Paper NO: 11 is acknowledged. All elected claims will be examined (where appropriate in part) drawn to SEQ ID NO: 2. It is presumed that applicant will amend the claims to properly draw the claims to SEQ ID NO: 2 only, as expressed in election of Group II.

Claim 3, 13 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter (rat regulatory element, i.e., non-elected SEQ ID NO: 1), there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: the description (p. 6, line 12) when referring to Fig. 4A (sheet 10/23) states that relative protein binding sites are illustrated by open circles and filled triangles. However, the actual figure does not contain any corresponding reference signs.

In addition Fig. 4D and E (sheets 12/23 and 13/23) are described as showing arrowheads indicating protein complexes. However the actual figures are so dark in some panels that it is impossible to discern any complexes. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claims 1 and 16-30 are objected to because of the following informalities: claims are drawn in part to non-elected subject matter. Claim 18 is drawn to non-elected subject matter and is withdrawn from further consideration. Appropriate correction is required.
4. Claim 5-12 and 15 objected to under 37 CFR 1.75(c) as being in improper form, because a multiple dependent claim cannot depend from any other multiple dependent claim. The claims cited refer to “any one of preceding claims” that in turn either depend from a claim that includes the phrase “any one of preceding claims” or depend from a claim that itself depends from a claim that includes the phrase. See MPEP § 608.01(n).
Accordingly, the claims have not been further treated on the merits.
5. Claims 22 and 30 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 and 30 encompass what has already been claimed in independent claims 16 and 25: a regulatory element that is inducible by a compound. Thus claim 22 and 30 merely restate the same.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2, 4, 16-17 and 19-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim(s) refer to or are dependent from claim(s) that refer to SEQ ID NO: 2 using the phrase “[R]egulatory element derived from the nucleotide sequence of SEQ ID NO: 2...” that functions in transcription induction. It is unclear whether applicant is claiming that any derivative of any length from SEQ ID NO: 2 would be encompassed by the claim(s). The disclosure teaches a single 466 bp fragment (i.e. SEQ ID NO: 2) thus even a single nucleotide could be encompassed by the claim if derived from SEQ ID NO: 2.

For the purposes of examination the claims will be given their broadest interpretation, meaning that the claim encompasses all derivatives from SEQ ID NO: 2 down to a single nucleotide. In other words, under such interpretation using “derived from” would mean that the claim would encompass any deletions, insertions or substitutions made to SEQ ID NO: 2, no matter to what degree (e.g. a ten-nucleotide fragment ‘derivative’ could be identical or highly homologous to a nucleotide stretch in SEQ ID NO: 2 and such a fragment may be essential for functionality).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 2, 4, 14 and 16-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The disclosure fails to state or teach one of ordinary skill in the art the exact functional domains within SEQ ID NO: 2 that would be necessary to effect inducible transcription of operably-linked heterologous polynucleotides. Applicants claims read on a genus of any regulatory elements derived from SEQ ID NO: 2 or having at least about 70 percent sequence identity to SEQ ID NO: 2. Thus the claims as written encompass a multitude of species.

The written description requirement for a claimed genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, by disclosure relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics sufficient to show applicant was in possession of the claimed genus.

As written the claims encompass or are dependent from claims that encompass a 466 bp sequence (SEQ ID NO: 2), including any derivative thereof resulting from insertion, deletion or substitution, having inducible transcriptional function; this would require that the functional domains contained therein be characterized to identify motifs involved in transcription induction. However the instant specification only teaches the full-length 466 bp sequence as having transcription regulatory activity. Applicant is claiming a genus with all potential species contained therein, while the specification does not teach a representative number of species.

The instant specification discloses clarification of functional domains within a homologous sequence, SEQ ID NO: 1: rat MnSOD regulatory element, down to 95 bp (Fig. 4E at 13/23). Notwithstanding that this data may suggest that homologous stretches, in human MnSOD regulatory element SEQ ID NO: 2, may function similarly, the specification is deficient in describing a structure-function relationship for all potential species derived from SEQ ID NO: 2. In any case, with regard to functionality, the clarification of SEQ ID NO: 1 is made down to a 95 bp region which itself may contain multiple functional domains. For the specification to teach representative species as encompassed by the claims, the 466 bp would have to be further clarified to identify potential functional domains contained therein. Prior art teaches that enhancers can be divided into several functional domains whereby each one may be required for optimal transcriptional activity. Moreover, even identified functional domains may have differential transcriptional activity that is limited based on cell or tissue-specificity.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 2, 4, and 14 are rejected under 35 USC § 102(b) as being anticipated by Wan et al, *Molecular structure and organization of the human manganese superoxide dismutase gene*. DNA Cell Biology (1994 Nov.) 13(11): 1127-36. Claims 1, 2 and 4 encompass SEQ ID NO: 2 and its function as a regulatory element capable of inducible transcription of an operably linked heterologous polynucleotide. Claim 14 further limits said regulatory element to any sequence having at least 70% identity to SEQ ID NO: 2. However, Wan teaches the exact same sequence of the human MnSOD gene (SEQ ID NO: 2) and characterizes the 5' regulatory region revealing that the region within 708 bp of the putative transcription initiation site contains no TATA box or CAAT box. Wan at 1130-1133.

Furthermore Wan teaches that the region includes multiple transcription binding sites within 400 bp of the initiation site, a stretch rich in GC, strongly suggesting the role of this region as a regulatory element. Applicants claim that the regulatory elements are "capable of" causing inducible transcription or expression of heterologous sequences operably linked thereto. Since Wan teaches the same sequence (SEQ ID NO: 2) the biological activities associated with said sequence would be inherent.

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Conclusion

As of this first office action the status of the claims is: claims 1, 2, 4, 14, 16, 17, and 19-30 are rejected. Claims 5-12 are objected to. Claims 3, 13 and 18 are withdrawn from further consideration. Applicant should note that where the same claims are rejected on one basis and objected to on another basis, rejections control so that claims are included in the rejection lot, however the objections for such claims need to also be addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 703-305-4454. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

Ray Akhavan
Patent Examiner
Art Unit 1636

RA
July 14, 2003


DAVID GUZO
PRIMARY EXAMINER